K124038

JUN 2 1 2013

510(k) Summary

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

June 20th, 2013

4. Device Identification

Trade/Proprietary Name:	Bedside Paediatric Early Warning System (BedsidePEWS™)
Common/Usual Name:	Accessory to multi-parameter patient monitor (bedside or ambulatory)
Classification Name:	Physiological Patient Monitor (without arrhythmia detection or alarms)
Classification Regulation:	870.2300
Product Code:	MWI
Device Class:	Class II
Classification Panel:	Cardiovascular

5. Predicate Devices

K053112 – BioSign (Oxford BioSignals Ltd)

6. Device Description

The product is a web-based clinical decision-support tool that can also be run as a stand-alone application for use on computers running Microsoft Software Operating features with a local network connection, which access medical data. It is also interfaces to other medical

automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), and Practice Management Software.

The software device consists of a SQL compatible database that provides access to the patient specific information and allows clinicians to input patient data (i.e. heart rate, respiratory rate, blood pressure, oxygen saturation, oxygen therapy, respiratory effort, and capillary refill time) to deliver actionable information, such as recommended follow-up and/or guideline for further and subsequent clinical assessments, and analytics of patients through real-time vital signs monitoring algorithm.

The software is installed on a network connected server with the following minimum requirements:

For server installation:

- Java Runtime Environment 1.6 or higher

For end users:

- Mozilla FireFox 3.6 or higher; Google Chrome 4.0 or higher; Safari 4.0 or higher; Opera 10.5 or higher, with JavaScript enabled
- 1024 x 768 screen resolution or higher.

7. Intended Use

The Bedside Paediatric Early Warning System (BedsidePEWS™) is an electronic documentation tool that is designed to be used in conjunction with multi-parameter patient monitoring. It is indicated for use by healthcare professionals with paediatric patients between the ages of term newborn (>37 weeks gestational age) and 18 years, who are hospitalized with any medical or surgical condition.

BedsidePEWS™ allows input by the healthcare professional of commonly recorded vital sign data and provides clinician with a patient status index (the "BedsidePEWS™ score") based on a weighted average of seven vital signs when entered by the clinician, namely Heart Rate, Respiratory Rate, Blood Pressure, Oxygen Saturation, Oxygen Therapy, Respiratory Effort, and Capillary Refill. The "BedsidePEWS™ score" is a single measure of a patient's condition and indicates the variation in the patient's vital signs with respect to normality. BedsidePEWS™ is an adjunct to and is not intended to replace vital signs monitoring.

BedsidePEWS™ is intended for use in wards and the emergency rooms in hospitals that provide care for children between the ages of term newborn (>37 weeks gestational age) and 18 years. It is not intended for use in the Neonatal Intensive Care Unit.

8. Comparison of Technological Characteristics

The following table compares the Bedside Paediatric Early Warning System (BedsidePEWS™) to the predicate device with respect to intended use, technological

characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	OBS Medical	Bedside Clinical System Inc.
Trade Name	Predicate BioSign™	New Device Bedside Paediatric Early Warning System (BedsidePEWS™)
510(k) Number	K053112	Not assigned
Product Code	MWI	MWI
Regulation Number	870.2300	870.2300
Regulation Name	Physiological Patient Monitor (without arrhythmia detection or alarms)	Physiological Patient Monitor (without arrhythmia detection or alarms)
Indications for Use	BioSign™ is an accessory to multi-parameter patient monitors (bedside or ambulatory) or clinical information systems and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine. BioSign™ provides the clinician with a patient status index based on a weighted average of five vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The patient status index is a single measure of a patient's condition and represents how different the patient's vital signs are with respect to normality. BioSign™ is an adjunct to and is not intended to replace vital sign monitoring and as such does not contain alarms, but alerts the physician to changes in the patient's physiological status.	The Bedside Paediatric Early Warning System (BedsidePEWS™) is an electronic documentation tool that is designed to be used in conjunction with multi-parameter patient monitoring. It is indicated for use by healthcare professionals with paediatric patients between the ages of term newborn (>37 weeks gestational age) and 18 years, who are hospitalized with any medical or surgical condition. BedsidePEWS™ allows input by the healthcare professional of commonly recorded vital sign data and provides clinician with a patient status index (the "BedsidePEWS™ score") based on a weighted average of seven vital signs when entered by the clinician, namely Heart Rate, Respiratory Rate, Blood Pressure, Oxygen Saturation, Oxygen Therapy, Respiratory Effort, and Capillary Refill. The "BedsidePEWS™ score" is a single measure of a patient's condition and indicates the variation in the patient's vital signs with respect to normality. BedsidePEWS™ is an adjunct to and is not intended to replace vital signs monitoring. BedsidePEWS™ is intended for use in wards and the emergency rooms in hospitals that provide care for children between the ages of term newborn (>37 weeks gestational age) and 18 years. It is not intended

Manufacturer	OBS Medical	Bedside Clinical System Inc.
Trade Name	Predicate BioSign™	New Device Bedside Paediatric Early Warning System (BedsidePEWS™)
		for use in the Neonatal Intensive Care Unit.
Material	Software	Software
Hardware Platform(s)	Windows PC with or without Touch Screen/ Tablet	Windows PC with or without Touch Screen/ Tablet
Compatible operating system (software only)	Windows XP, Windows 7, Windows Server 2003 .NET 3.5 SP1	Windows XP, Windows 7, Windows Vista
Minimum memory requirements (software only)	1GB	1GB
Display type	PC or Computer Tablet	PC or Computer Tablet
Data acquisition	Continuous	BedsidePEWS™ is capable of taking periodic vital signs information from Electronic Medical Record systems or entered via a keyboard.
Parameters	HR, RR, T, BP and SpO2	HR, RR, BP, and SpO2, Resp. Effort, CRT and O2 therapy
Ability to display multimodality images	Yes	Yes
User-interface	Yes	Yes
Web-based browser	Yes	Yes
Ability to trend	Yes	Yes
Ability to obtain information from the HIS (e.g. HL7)	Yes	Yes
Interfaces to electronic record (EHR)	Yes	Yes
Security and Encryption	Software is fully HIPPA compliant.	Software is fully HIPPA compliant.
Use environment	Hospital	Hospital
Intended users (target population)	Professional Users	Professional Users

Bedside Clinical Systems' BedsidePEWS clinical decision support system is a medical device and has similar indications for use statement as the predicate device. The differences do not alter the intended decision support –both devices have essentially the same intended use.

The device also has similar technological characteristics as the predicate device. Both devices use software to process the condition scores. Both clinical decision support systems are statistically derived. While the details of the process are different, the basic technology is the same. Since the comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficiently precise to assure equivalence, performance data are provided from the published literature. The results of the performance testing demonstrate substantial equivalence.

9. Non-Clinical Performance Data

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. The BedsidePEWS device passed all testing and supports the claims of substantial equivalence and safe operation.

10. Clinical Testing

Clinical evaluation of the BedsidePEWS was performed to ensure that the BedsidePEWS software was clinically useful, and would be accepted by the clinical users.

The validation of the Bedside PEWS score using the 7-item score successfully quantified severity of illness in routinely monitored hospitalized children and identified critically ill children with at least one hours notice. Overall, the results support that the device can be used to identify a pediatric patient at risk while undergoing routine monitoring in the hospital.

11. Statement of Substantial Equivalence

The Bedside Paediatric Early Warning System (BedsidePEWS™) has similar intended use as the predicate device and that any technological differences between the Bedside Paediatric Early Warning System (BedsidePEWS™) software and the predicate device do not raise any questions regarding Bedside Paediatric Early Warning System (BedsidePEWS™)'s safety and effectiveness.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 21, 2013

Bedside Clinical Systems Inc
Diane Sudduth
611 West 5th Street, Third Floor
Austin, TX 78701 US

Re: K124038
Trade/Device Name: Bedside Paediatric Early Warning System (BedsidePEWS)
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: May 28, 2013
Received: May 29, 2013

Dear Diane Sudduth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 4 - Indications for Use Statement

510(k) Number (if known): K124038

Device Name: Bedside Paediatric Early Warning System (BedsidePEWS™)

Indications for Use:

The Bedside Paediatric Early Warning System (BedsidePEWS™) is an electronic documentation tool that is designed to be used in conjunction with multi-parameter patient monitoring. It is indicated for use by healthcare professionals with paediatric patients between the ages of term newborn (>37 weeks gestational age) and 18 years, who are hospitalized with any medical or surgical condition.

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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